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Supreme Court, U.S.
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No. 96-603

In the Supreme Court of the United States

OCTOBER TERM, 1996

CATHERINE W. GRIFFIN, PETITIONER

v.

MEDTRONIC, INC., RESPONDENT

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

SUPPLEMENTAL BRIEF FOR THE RESPONDENT

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SUPPLEMENTAL BRIEF FOR THE RESPONDENT

Pursuant to Rule 15.8 of the Rules of this Court, respondent respectfully draws to this Court's attention several significant developments that have occurred since the filing of our brief on December 30, 1996. These developments demonstrate not only that certiorari should be granted, as both petitioners and we have urged, but also that this Court's review should be plenary rather than summary. Even if the Court is disposed to act summarily, this case should be held pending resolution of the petition for a writ of certiorari in *Iolab Corp.* v. *Hunter*, No. 96-1126 (filed Jan. 15, 1997), which raises closely related issues concerning the scope of express preemption under the Medical Device Amendments ("MDA") to the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a).

1. In *Martin* v. *Telectronic Pacing Systems, Inc.*, 1997 U.S. App. LEXIS 1627 (Jan. 31, 1997), the Sixth Circuit on remand from this Court[1] recently held that the MDA expressly preempts a variety of damages claims brought against the manufacturer of an investigational device, including claims under Ohio law for defective manufacture, defective design, failure to warn, express warranty, and loss of consortium. The Sixth Circuit candidly acknowledged that its holding is in conflict with the post-*Lohr* decision of Missouri's highest court in *Connelly* v. *Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996), which held that "causes of action for negligence, strict liability, failure to warn, lack of informed consent, and fraud were *not* preempted in a case involving an * * * investigational device." *Martin*, 1997 U.S. App. LEXIS 1627, at *23 n.6 (emphasis added). The Sixth Circuit's decision thus significantly worsens the division in the lower courts (see Resp. Br. 14 n.10) concerning how *Lohr* should be applied to investigational devices.

The Sixth Circuit's decision also confirms our prediction (see Resp. Br. 28-29) that the lower courts would continue to have great difficulty understanding and applying this Court's fractured decision in *Lohr*. Even before *Martin* the lower courts were

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[1] 116 S. Ct. 2576 (1996) (granting petition, vacating decision below, and remanding for reconsideration in light of *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996)).

deeply divided over whether the holding in *Lohr* hinged on the absence of a *conflict* or rather on the absence of federal and state requirements of sufficient *specificity*. See Resp. Br. 10-12. The Sixth's Circuit's decision is likely to compound this confusion because it treats the "specificity" and "conflict" rationales as *alternative means* by which a federal requirement may qualify to trigger preemption (or a state requirement may qualify to be subject to preemption).

The Sixth Circuit reasoned that, "[u]nlike the general federal requirements discussed in [*Lohr*], the [federal] regulations governing investigational devices are essentially device specific" and therefore trigger preemption under the MDA. *Martin*, 1997 U.S. App. LEXIS 1627, at *19; see also *id.* at *25, *30. On the other hand, when it came to evaluating the alleged *state* common law and statutory requirements underlying plaintiff's various product-liability and other claims, the Sixth Circuit relied on the "conflict" rationale in holding that those state requirements were subject to preemption:

> [I]t is questionable whether the [Ohio product liability statute] is "with respect to" a medical device and not simply of general applicability. In [*Lohr*], the state common law requirements regarding manufacturing were not specifically developed "with respect to" medical devices and were not the kinds of requirements that would impede the implementation and enforcement of specific federal requirements. [*Lohr*] at 2258. The state requirement regarding negligent manufacturing was simply "the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products." *Id.* at 2258. The same cannot be argued with respect to the generally applicable statute in question [here] because it is the kind of requirement that would *impede the implementation and enforcement of specific federal requirements*. *Id.*

Id. at *25-*26 (emphasis added).[2] Compare, *e.g.*, *Dutton* v. *Acro-*

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[2] See also 1997 U.S. App. LEXIS 1627, at *28-*29 (design defect claim is preempted even though it imposes requirements that "appear[ ] not specifically applicable solely to medical devices," because to permit claim to proceed "would impede the implementation and enforcement of

med Corp., 1997 Ohio App. LEXIS 97, at *14 (8th Dist. Ct. App. Jan. 16, 1997) (in rejecting argument that state failure-to-warn claim is preempted by MDA, stating that "these state requirements escape preemption because they apply to all products generally, not only to medical devices").

What is more, the Sixth Circuit's discussion of the "specificity" test as applied to the federal regulations governing investigational devices strongly confirms the essential indeterminacy of that concept. As we explained (Resp. Br. 12-13), the concept of "device-specificity" is susceptible to multiple interpretations. It could mean that the requirement relates only to medical devices and not to other kinds of products. See Resp. Br. 13. It could mean that the requirement is limited to a single device (such as one model of pacemaker made by a particular manufacturer) or to one type of device (such as all pacemakers). *Ibid.* It could mean that the requirement is imposed on the device itself (as opposed to the manufacturer or the manufacturing site). *Ibid.* Or it could mean that the requirement is narrow or specific in its content or command. *Ibid.* In holding that the federal requirements relating to investigational devices are "device-specific" and thus trigger preemption, the Sixth Circuit added even more candidates to this list of possible interpretations.

For example, the court explained that the federal regulations at issue "specifically apply to investigational devices," thereby suggesting that requirements that target a *regulatory class* of devices qualify as "device-specific." *Martin*, 1997 U.S. App. LEXIS 1627, at *25; see also *id.* at *30 ("Unlike in *Medtronic*, the labeling requirements here are specific in that they apply only to investigational devices; they are not, therefore, generic requirements."). The Sixth Circuit also reasoned that the federal requirements concerning design and manufacturing had become "specific" because the FDA had conducted an extensive review of the specific device in question and had approved it for an investigational exemption. *Id.* at *25, *28. The Sixth Circuit thereby

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specific federal requirements"); *id.* at *31 (failure-to-warn claim is preempted because it would impose requirements that would "impede" federal interests).

suggested that federal requirements that are applicable to many kinds of devices might become "device-specific" if applied to a particular device through a process of extensive regulatory review. But see *Dutton*, 1997 Ohio App LEXIS 97, at *12-*13 (rejecting argument that FDA's specific action with respect to labeling of a particular Section 510(k) device triggers preemption).

In sum, the Sixth Circuit's decision illustrates the serious ambiguities in *Lohr* and will no doubt contribute to the growing doctrinal confusion and uncertainty in this important area of the law.

2. On January 15, 1997, a petition for a writ of certiorari was filed seeking review of the Missouri Supreme Court's decision in *Connelly* v. *Iolab Corp.*, *supra*. *Iolab Corp.* v. *Hunter*, No. 96-1126. We continue to believe that the present case, *Griffin* v. *Medtronic, Inc.*, is the ideal vehicle to reconsider *Lohr* (see Resp. Br. 29-30). Nevertheless, if review is granted in *Iolab* to resolve the clear conflict between the Missouri Supreme Court and the Sixth Circuit, then this Court will have occasion to consider some of the issues that were left undecided in *Lohr* and to clarify, and perhaps to modify, some of the analysis in *Lohr*. For example, *Iolab* (if granted) would give the Court an opportunity to address the question — squarely raised in the present case as well — whether it is appropriate to apply *Chevron* deference to an agency interpretation of an express preemption clause. It would also give the Court an occasion to reconsider the many aspects of *Lohr* that are ambiguous or problematic.

Accordingly, we respectfully request that, if plenary review is not granted in this case, the Court hold this case pending its disposition of the petition in *Iolab Corp.* v. *Hunter*.

CONCLUSION

The petition for a writ of certiorari should be granted, or at minimum, this case should be held pending the disposition of the certiorari petition in *Iolab Corp.* v. *Hunter*, No. 96-1126.

Respectfully submitted.

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